

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Efficacy of eye Movements Desensitization and Reprocessing on the Psychological Well-being of the Patients with chronic renal failure under Hemodialysis

Protocol summary

Study aim

Determining the effect of eye movement desensitization and reprocessing on the psychological well-being of chronic renal failure patients undergoing hemodialysis.

Design

In this experimental clinical trial study, 90 patients with chronic renal failure undergoing hemodialysis were selected as simple and randomly divided into two intervention and control groups by block method.

Settings and conduct

In the current study, the research environment will be Hajieh Narges Mahshahr Hospital. The method consists of 8 steps. The first step is to identify traumatic events with the cooperation of the patient, the second step is to explain the process and preparation, the third step is to identify positive thoughts from the patient, the fourth step is to desensitization, the fifth step is to create positive cognition, the sixth step is to process, the seventh step is to end the sessions and the eighth step is to re-evaluate. be

Participants/Inclusion and exclusion criteria

Inclusion criteria: giving informed consent - being between 15 and 60 years old having a history of hemodialysis treatment for more than three months
Exclusion criteria: having history of mental illness - visual impairment- having addictions

Intervention groups

Intervention group: For the intervention group, the researcher performed desensitization with eye movements and reprocessing three times a week for 4 weeks in a row in 30-45 minutes sessions after performing hemodialysis in a room previously coordinated with the hospital authorities. will, does.
Control group: For the control group, there will be no intervention except for routine medical care and support of these people by their families. After the intervention, psychological well-being components were measured in

both groups.

Main outcome variables

psychological well-being

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220529055015N1**

Registration date: **2023-01-24, 1401/11/04**

Registration timing: **prospective**

Last update: **2023-01-24, 1401/11/04**

Update count: **0**

Registration date

2023-01-24, 1401/11/04

Registrant information

Name

zahra ghasemirad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 4362 1653

Email address

saya.rad64@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-30, 1401/11/10

Expected recruitment end date

2023-05-20, 1402/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of eye Movements Desensitization and Reprocessing on the Psychological Well-being of the Patients with chronic renal failure under Hemodialysis

Public title

Efficacy of eye Movements Desensitization and Reprocessing on the Psychological Well-being

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

having consent informed to enter the study Patients who undergo regular hemodialysis three times a week. Has a history of hemodialysis treatment for more than three months Age between 15 and 60 years

Exclusion criteria:

Having history of seizures Having mental illnesses Having addictions Having vision problems

AgeFrom **15 years** old to **60 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **90****Randomization (investigator's opinion)**

Randomized

Randomization description

The samples were divided into two groups through a random block allocation process. In order to create the sequence and concealment, the online software with the following address will be used, and a special randomization code will be generated. Sealed Envelope Ltd. 2021. Create a blocked randomisation list. [Online] Available from: <https://www.sealedenvelope.com/simple-randomiser/v1/lists> [Accessed 18 Jun 2022 To perform this method, the number of intervention groups (two groups A and B), the size of each block (blocks of 6) and the number of sample size (90 samples) were entered in the mentioned site. Then the site presented a list with 15 blocks of 6. In this study, we use blocks of 6, and the website performs randomization and assigns numbers to the blocks.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Yasouj University of Medical Sciences

Street address

Shahid Motahari Blvd.- Yasouj University of Medical Sciences-Yasouj

City

Yasuj

Province

Kohgiluyeh-va-Boyerahmad

Postal code

7591994799

Approval date

2022-03-14, 1400/12/23

Ethics committee reference number

IR.YUMS.REC.1400.204

Health conditions studied**1****Description of health condition studied**

Psychological well-being

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Psychological well-being

Timepoint

Before the intervention and immediately after the intervention

Method of measurement

Psychological well-being questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The study will be done in both morning and evening shifts at Hajieh Narges Mahshahr Hospital. Then, for the intervention group, the researcher will perform EMDR treatment three times a week for 4 weeks in a row in 30-45 minutes sessions after hemodialysis in a room previously coordinated with the hospital authorities. After the intervention, psychological

well-being components will be measured again in this group. The method of desensitization with eye movements and reprocessing consists of 8 steps: First step: the traumatic scene or scenes will be identified with the cooperation of the patient and the researcher. Then, with the cooperation of the patient, the most uncomfortable traumatic scene is selected. The second stage (explanation and preparation): creating a therapeutic alliance, explaining the process of desensitization with eye movements and reprocessing, explaining the effects of the desensitization method with eye movements and reprocessing, explaining treatment expectations and preparing clients. The third stage (examination): In this stage, the client is asked to visualize the scene or incident that creates the most positive and peaceful feeling in his mind. The fourth stage (desensitization of the target): focusing on the negative belief. The client moves the therapist's fingers quickly and simultaneously to the left and right in front of him, asking the client to follow the movements of the fingers with only eye movements. The fifth stage (creating positive cognition): cognitive reconstruction, strengthening the client's positive belief to replace the negative belief. The sixth stage (body processing): asking the helper to join and maintain the target event at the same time and recognizing the positive word and checking the muscle tension. The seventh stage (ending the sessions): asking the client to express the disturbing image, thoughts or emotions experienced. During the treatment, remember the events experienced in the treatment process in the form of thoughts, conditions, dreams, memories and other issues in the notebook. The eighth stage (re-evaluation): evaluation of previously processed goals (evaluation of the main variable). Visual tracking of the movement of the therapist's finger in the same state that the patient imagines the traumatic scene one after another - the patient must follow the rapid movements of the therapist's finger, which is across his field of vision, with rapid eye movements. The therapist's finger should be approximately 30 cm away from the subject's eyes and move from right to left and vice versa in the patient's field of vision. This movement consists of going back and forth twice in one second, which is considered one cycle, and every 12-24 cycles is one set. After each set, the therapist tells the patient to stop visualizing the scene and lean back in his chair and take a deep breath. This process is repeated several times according to the needs and motivation level of the patient.

Category
Behavior

2

Description

Control group: In the control group, there will be no intervention other than routine medical care and support of these people by their families. Routine interventions include nursing care before, during and after hemodialysis, which can also include nursing consultations. Continuing to use medications prescribed by doctors.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Hajiya Narges Hospital in Mahshahr

Full name of responsible person

Mohammad Behnammoghadam

Street address

in front of Haj Ebrahim School, Motahari street

City

Mahshahr

Province

Khouzestan

Postal code

7591994799

Phone

+98 61 5232 2082

Email

mbehnam1363@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Dr. Hossein marioryad

Street address

Shahid Motahari Blvd.- Yasouj University of Medical Sciences, Yasouj

City

Yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

7591994799

Phone

+98 74 3333 7230

Email

mbehnam1363@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yasouj University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Phone

+98 74 3333 7230

Email

mbehnammoghdam@gmail.com

Person responsible for general inquiries**Contact****Name of organization / entity**

Yasouj University of Medical Sciences

Full name of responsible person

Mohammad Behnammoghadam

Position

Faculty Member

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Shahid Motahari Blvd.- Yasouj University of Medical Sciences, Yasouj

City

Yasuj

Province

Kohgiluyeh-va-Boyerahmad

Postal code

7591994799

Phone

+98 74 3333 7230

Email

mbehnammoghdam@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Yasouj University of Medical Sciences

Full name of responsible person

Mohammad Behnammoghadam

Position

Faculty Member

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Shahid Motahari Blvd.- Yasouj University of Medical Sciences, Yasouj

City

Yasuj

Province

Kohgiluyeh-va-Boyerahmad

Postal code

7591994799

Phone

+98 74 3333 7230

Email

mbehnammoghdam@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Yasouj University of Medical Sciences

Full name of responsible person

Mohammad Behnammoghadam

Position

Faculty Member

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Shahid Motahari Blvd.- Yasouj University of Medical Sciences, Yasouj

City

Yasuj

Province

Kohgiluyeh-va-Boyerahmad

Postal code

7591994799

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable